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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,649	08/18/2003	Jack Chu	PA1515 (MEDT/0018)	5247

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EXAMINER	
NEAL, TIMOTHY J	
ART UNIT	PAPER NUMBER
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,649	CHU ET AL.	
	Examiner	Art Unit	
	Timothy J. Neal	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/31/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29 and 31-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29 and 31-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 October 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to applicant's amendment received on 10/31/2006.

Drawings

The drawings were received on 10/31/2006. Figures 7C and 7D are acceptable. Figures 3C and 3D are not acceptable because new matter has been added. The configuration of the two helices and three helices is not supported by the original disclosure. The Applicant has stated that the terms "double helix" and "triple helix" are well known to persons having ordinary skill in the art. The Examiner contends that the additional drawings are not necessarily the only interpretations of double and triple helices. A double helix is generally regarded as having two opposing coils that are wound in opposite directions. The replacement drawings show two helices wound in the same direction. Furthermore, claims 4 and 5 do not recite double and triple helices. They recite "two helices" and "three helices" with no mention of the double and triple helices of the specification. These multiple helices can be in any configuration and are not limited to the drawings submitted by the Applicant. Therefore, the Examiner considers these drawings to contain new matter. Because these figures have not been accepted, new drawings are required as stated below.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "two helices" and

"three helices" of claims 4 and 5 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 46 is objected to because of the following informalities: the claim recites language such as "the a substantial portion" and needs to be made generally more clear. Appropriate correction is required.

Applicant's arguments, see page 20, filed 10/31/2006, with respect to the rejection(s) of claim(s) 6, 42, 46 and 47 under USC 102 and 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Gerberding, Falotico, and Ragheb as stated below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7-12, 17-19, 40, 41, and 43-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Ragheb et al. (U.S. 6,096,070).

Regarding **claim 1**, Ragheb et al. discloses a stent (Fig. 1 Item 12) locatable interior of an aneurysmal site in a blood vessel; wherein the stent supports the aneurysmal site upon deployment, contracts when the aneurysmal site contracts, and comprises at least one therapeutic agent (Col 3 Lines 26-39).

Regarding **claim 2,** Ragheb et al. discloses the stent having a helical configuration (Col 6 Lines 39-42 and Col 15 Line 56).

Regarding **claim 3,** Ragheb et al. discloses the stent comprising at least one helix (Col 6 Lines 39-42 and Col 15 Line 56).

Regarding **claim 7,** Ragheb et al. discloses the stent comprising a polymer (Col 7 Lines 29-47).

Regarding **claim 8,**Ragheb et al. discloses the polymer being biodegradable (Col 7 Lines 29-47).

Regarding **claim 9,** Ragheb et al. discloses the polymer being cellulose acetate (Col 7 Lines 29-47).

Regarding **claim 10,** Ragheb et al. discloses the therapeutic agent being covalently linked to the polymer (Col 8 Line 25).

Regarding **claim 11,** Ragheb et al. discloses the polymer being not biodegradable (Col 7 Lines 29-47).

Regarding **claim 12,** Ragheb et al. discloses the polymer being polyurethane (Col 7 Lines 29-47).

Regarding **claim 17,** Ragheb et al. discloses the stent comprising metal (Col 7 Lines 29-47).

Regarding **claim 18,** Ragheb et al. discloses the metal being a metal alloy (Col 7 Lines 29-47).

Regarding **claim 19,** Ragheb et al. discloses the metal alloy being NiTi (Col 7 Lines 29-47).

Regarding **claim 40,** Ragheb et al. discloses the stent being formed by laser cutting (Col 16 Line 51).

Regarding **claim 41,** Ragheb et al. discloses the stent being deployed by a catheter (Col 10 Line 63).

Regarding **claim 43**, Ragheb et al. discloses a helical stent locatable interior of an aneurysmal site in a blood vessel; wherein the stent supports the aneurysmal site upon deployment, contracts when the aneurysmal site contracts, and comprises at least one therapeutic agent (Col 19 Lines 22-27).

Regarding **claim 44**, Ragheb et al. discloses the stent being biodegradable (Col 7 Lines 29-47).

Regarding **claim 45**, Ragheb et al. discloses the stent comprises poly(orthoester) (Col 7 Lines 29-47).

Claims 1, 31, 38, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Hunter et al. (U.S. 5,716,981).

Hunter discloses coated stents, wherein the coating comprises a polymer and a therapeutic agent (Column 1, Lines 14-16). Hunter also discloses polymers including polytlactic acid) and polycaprolactone (column 7); microsphere and size ranges of up to approximately 120 microns (figures 5-6, 9-10), and release profiles of the therapeutic agent including about 1% to about 25% of the therapeutic agent released in the first 10 days (figure 15D).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. in view of Solem et al (U.S. 6,210,432).

Ragheb et al. discloses the invention substantially as claimed as stated above.

Regarding **claims 4 and 5**, Ragheb et al. does not disclose the stent comprising two helices or the stent comprising three helices. Solem et al. teaches a stent comprising two helices (Fig. 3) and comprising three helices (Col 3 Lines 41-43). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Ragheb et al.'s stent to include Solem et al.'s helix configurations. Such a modification would allow the stent to bend as necessary. Also, the Examiner notes that the Applicant stated on page 11 of the arguments received on 10/31/2006 that double and triple helices were well understood in the art. The Examiner can only assume that if they are well understood, they must be well known in the art prior to the Applicant's filing date. This also renders the claims obvious.

Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. in view of Eisert (U.S. 2005/0192664).

Ragheb et al. discloses the invention substantially as claimed as stated above.

Regarding **claims 13and 14**, Ragheb et al. does not disclose the polymer being a pH-sensitive polymer. Eisert teaches a pH sensitive polymer (Paragraph 64) that expands when contacted with a certain pH. Eisert does not name the polymers listed in claim14, however, the polymers listed in claim 14 are well known in the art to be temperature sensitive polymers. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Ragheb et al.'s polymer stent to include Eisert's pH-sensitive polymer. Such a modification would allow the stent to expand.

Regarding **claims 15 and 16**, Ragheb et al. does not disclose the polymer being a temperature-sensitive polymer. Eisert teaches a temperature sensitive polymer (Paragraph 65) that takes on a new shape when heat is applied. Eisert does not name the polymers listed in claim16, however, the polymers listed in claim 16 are well known in the art to be temperature sensitive polymers. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Ragheb et al.'s polymer stent to include Eisert's temperature sensitive polymer. Such a modification would allow the stent to change shape upon application of heat.

Claims 6, 10, and 20-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al.

Ragheb et al. discloses the invention substantially as claimed as stated above.

Should the Applicant further contest the Examiner's claim that Ragheb anticipates claim 13, an obviousness rejection is also provided. A person having ordinary skill in the art would reasonably be capable of using the teachings of Ragheb that heparin can be covalently linked to a polymer to covalently link heparin directly to the polymer of the stent. The Examiner considers this to be within the purview of a person having ordinary skill in the art at the time the invention was made to modify Ragheb's polymer stent to include covalently linked heparin directly to the base material. Such a modification would bond the heparin to the stent in a suitable fashion allowing it to act as a thrombin inhibitor.

Ragheb does not explicitly disclose the stent being self-expanding. The Examiner considers self-expanding to stents to be old and well known in the art. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Ragheb's stent to be self-expanding. The advantage of self-expanding stents is that they may be delivered without the use of a balloon simplifying delivery.

Ragheb et al. does not disclose the therapeutic agents claimed in claims 20-27. However, the agents claimed in claims 20-27 are well known in the art and well known in the art for the treatment of various vascular deficiencies. Ragheb et al. discloses the stent being coated with a therapeutic agent. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Ragheb et al.'s therapeutic agent to include the agents claimed in claims 20-27. Such a modification would apply therapeutic agents at the site of injury.

Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. in view of Sparer et al. (U.S. 2004/0127978).

Ragheb et al. discloses the invention substantially as claimed as stated above.

Regarding claim 28, Ragheb et al. does not disclose the therapeutic agent being contained in a microsphere associated with the polymer. Sparer et al. teaches the therapeutic agent being contained in a microsphere associated with the polymer (Paragraph 88). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Ragheb et al.'s therapeutic agent to be contained in Sparer et al.'s microsphere. Such a modification allow for more precise control over release of the agent.

Regarding claim 29, Ragheb et al. does not disclose the microspheres being about 50 nm to 500 micrometers in size. Sparer et al. teaches the microspheres being about 50 nm to 500 micrometers in size (Paragraph 88) and being applied as a spray (Paragraph 97). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Ragheb et al.'s therapeutic agent to be contained in Sparer et al.'s microspheres of the given dimensions. Such a modification would allow for control over the release of the agent.

Claims 31, 32, 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. in view of Vallana et al. (U.S. 2003/0028242).

Ragheb et al. discloses the invention substantially as claimed as stated above. Ragheb further disclosesthe therapeutic agent being applied as a coating to the stent (Abstract and Column 7 Lines 55-62);the coating being applied as a film (Col 18 Line 2); a second coating deposed over the therapeutic coating (Fig. 2 Item 20); at least two therapeutic coatings, wherein each therapeutic coating is separated by a second coating (Fig. 2 Items 18, 22, and 24); the coating being a biodegradable coating (Col 9 Lines 20-67); the polymer being heparin (Col 9 Line 23); the coating being a time release coating (Col 10 Lines 30-35).

Ragheb et al. does not disclose the therapeutic coating further comprising a polymer. Vallana teaches that polymers are used as carriers for therapeutic coatings (Paragraph 65). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Ragheb's coating to include Vallana's polymer. Such a modification provides the advantage of additional control over the release characteristics of the drug. Furthermore, the polymer carrier coating of Vallana is considered a time-release coating being that the therapeutic agent is released over time.

Claims 39 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. in view of Vallana et al. further in view of Sparer.

Ragheb and Vallana do not disclose the time-release coating releasing from about 1% to about 25% of the therapeutic agent within 10 days after deployment. Sparer et al. teaches the time-release coating releasing from about 1% to about 25% of

the therapeutic agent within 10 days after deployment (Fig. 1). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Ragheb and Vallana's coating to include Sparer et al.'s release characteristics. Such a modification would allow the agent to be applied to the deficiency over a period of time and not all at once.

Regarding claim 48, Ragheb and Vallana do not disclose the microspheres being between 0.1 micrometers to about 100 micrometers in size. Sparer et al. teaches the microspheres being about 50 nm to 500 micrometers in size (Paragraph 88) and being applied as a spray (Paragraph 97). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Ragheb and Vallana's therapeutic agent to be contained in Sparer et al.'s microspheres of the given dimensions. Such a modification would allow for control over the release of the agent.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. in view of Vallana et al. further in view of Tartaglia et al. (U.S. 5,637,113).

Ragheb and Vallana disclose the invention substantially as claimed as stated above. Ragheb and Vallana do not disclose the film being from 10 micrometers to 5 millimeters thick. Tartaglia et al. teaches a therapeutic coating consisting of a film from 0.0015 inch to 0.002 inch thick (Col 7 Line 40). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Ragheb and Vallana's coating to include Tartaglia et al.'s film of given dimensions.

Such a modification would make the film thin enough so as to not add significant dimension to the stent.

Claims 42, 46, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerberding (U.S. 6,790,224) in view of Falotico et al. (U.S. 2003/0060877).

Gerberding discloses a method of treating an aneurysm comprising deploying to an aneurysmal site (Fig. 2).

Gerberding also discloses deploying a stent graft to exclude the aneurysm the a substantial portion of device of Claim 1 being disposed between the stent graft and the wall of the aneurysm (Fig. 2 Items 16 and 18).

Gerberding does not disclose the stent comprising a therapeutic agent and the method wherein the therapeutic agent is inactive until it comes in contact with an activating agent. Falotico et al. teaches a therapeutic agent on the inner surface of a stent (Fig 7) and a therapeutic agent being inactive until it comes in contact with an activating agent (Paragraph 142). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Gerberding's agent to include the therapeutic agent and the activation characteristic of Falotico et al. Such a modification would provide a therapeutic agent in contact with the blood stream to prevent clotting and allow for additional measure of time release.

Response to Arguments

Applicant's arguments filed 10/31/2006 have been fully considered but they are not persuasive with regards to claims 1-5, 7-29, 31-41, and 43-45.

The Applicant has argued that the Ragheb reference does not anticipate a stent that contracts when the aneurysmal site contracts. The Applicant contends that the reference, in fact, teaches away from such a limitation. The Examiner respectfully disagrees. Although the Ragheb reference is intended to maintain the patency of a vessel lumen, the structure will contract when an aneurysmal site contracts. The claim does not exclude external forces that may cause an aneurysm to contract. When a certain amount of force is applied at the aneurysm site, by a vice or during a car accident for example, the stent of Ragheb will contract. The Ragheb stent is not capable of withstanding an infinite amount of force. Therefore, the structure of the Ragheb stent is capable of meeting the functional limitation of independent claims 1, 42, and 43. Also, self-expanding stents are well known. These stents are generally compressed for insertion into a catheter. Clearly, any self-expanding stent is capable of being compressed when enough force is applied.

The Applicant has also argued that the therapeutic agent of Ragheb is not covalently linked to the polymer. The Applicant has stated that the outermost layer of item 12 is not the base material. Claim 10 depends from claim 8 which depends from claim 7. Claim 7 states that the stent comprises a polymer and claim 8 states that the polymer is biodegradable. The claims make no reference to the base material of the stent. The open-ended nature of the word comprising encompasses any portion of the

stent, including any polymer layers on the base material. The Examiner has also considered this limitation obvious. The Ragheb reference teaches covalently linking a therapeutic agent, heparin, to a polymer. A person having ordinary skill in the art would reasonably be able to covalently link heparin to the polymer base.

The Applicant has amended claim 31 to include the limitation that the therapeutic coating further comprise a polymer. The Vallana reference teaches that polymers function as carriers of active agents. The combination of Vallana and Ragheb renders the claim obvious. Although the Ragheb reference uses layers of polymers to control the dispersal of the therapeutic agents, a person having ordinary skill in the art would view this as an alternative to the known practice disclosed in Vallana. Using an alternative means for obtaining a similar objective is not viewed as a teaching away. Using a polymer carrier for drugs and using separate polymer layers adjacent to drugs in order to control the release characteristics of the drugs are known in the prior art as disclosed in the cited references. The Examiner considers it within the purview of a person having ordinary skill in the art to combine these references to reach a desired drug release control level.

The Applicant has also argued that the Hunter reference teaches away from a stent locatable within an aneurysm that contracts when the aneurysm contracts. The Examiner's reasoning from above also applies to the Hunter reference.

The Applicant also argued that the Ragheb reference does not necessarily state that the stent is self-expanding. The Examiner considers self-expanding stents to be old and well known in the art and obvious to a person having ordinary skill in the art.

The Applicant also argued that the Ragheb reference does not disclose a helical configuration. The statements made by the Examiner in the obviousness rejection were incidental and have been corrected. Because the Applicant only pointed to the Examiner's statements and not the reference itself, the Examiner considers the correction to sufficiently clarify the matter.

The Applicant's arguments against the Examiner's obviousness rejections are based on the primary reference being deficient as stated above. The Examiner has explained the reasoning as to why the primary reference is not deficient above. Because no other substantive arguments were made regarding the obviousness rejections, the Examiner considers the explanation regarding the primary reference to be sufficient.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cottone et al (US 2002/0116044) discloses a stent designed to contract as blood pulsates through the vessel. The Examiner considers this reference relevant because it discloses a prior art stent designed to contract and not simply maintain the patency of a lumen.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN

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12/22/06